UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

DEBRA CASCIO, an individual; and DAN CASCIO, an individual, *Plaintiffs* *v.* JOHNSON & JOHNSON, a New Jersey corporation; and JOHNSON & JOHNSON CONSUMER, INC., a New Jersey corporation, *Defendants*	**COMPLAINT** CASE NO.: *Jury Trial Demanded*

I. Introduction

1. Plaintiff Debra Cascio asserts personal-injury claims centering on recalled, benzene-contaminated NEUTROGENA® aerosol sunscreen. This sunscreen is regulated as an over-the-counter drug by the FDA. NEUTROGENA® sunscreen is designed, marketed, promoted, manufactured, distributed, and sold by the multinational conglomerate Johnson & Johnson through one or more of its subsidiaries or intermediaries, including but not limited to Johnson & Johnson Consumer Inc.

2. This Complaint states causes of action under theories of product liability, negligence, breach of warranty, and misrepresentation.

II. Parties, Jurisdiction, and Venue

3. Plaintiff Debra Cascio is an adult citizen, resident, and domiciliary of Marietta, Georgia.

4. Plaintiff Dan Cascio is also an adult citizen, resident, and domiciliary of Marietta, Georgia.

5. Johnson & Johnson is a foreign corporation organized and existing under the laws of New Jersey. J&J has its worldwide headquarters, principal place of business, and corporate nerve center, located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual business units to coordinate the development, manufacture, testing,

marketing, promotion, training, distribution, and sale of its products. Within J&J there are three sectors, medical devices & diagnostics, pharmaceutical, and consumer.

6. Defendant Johnson & Johnson Consumer Inc., ("J&J Consumer") is a New Jersey corporation with its headquarters and principal place of business at Grandview Road, Skillman, New Jersey, 08558. Johnson & Johnson Consumer Inc. manufactures, markets, advertises, labels, distributes, and sells the recalled sunscreen products at issue.

7. Johnson & Johnson and Johnson & Johnson Consumer Inc., are collectively referred to as "J&J" or "Defendants."

8. At all times relevant herein, J&J was engaged in the business of placing the recalled sunscreen products into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and selling such products.

9. Upon information and belief, Johnson & Johnson Consumer Inc., is a mere alter ego that acts under the sole direction and control of the officers and directors of the global J&J conglomerate. Johnson & Johnson is liable for the actions and inactions effectuated under the mask of Johnson & Johnson Consumer Inc. Johnson & Johnson and Johnson & Johnson Consumer Inc., at all times relevant operated as mere alter egos or instrumentalities of each other. There is such a unity

of interest and ownership between them that the separate corporate personhoods cease to exist. Defendants operate on paper as multiple companies but pragmatically as a single enterprise, controlled from the top down by the officers, executives, agents, and directors of Johnson & Johnson. Upon information and belief, Defendants have commingled their assets and funds, disregarded corporate formalities, reorganized corporate structure, and used subsidiary and intermediary entities to defeat justice, perpetuate fraud, and evade or diminish contractual and tort liability. Defendants acted in all respects as agents or apparent agents of one another.

10. There is complete diversity of citizenship here between Plaintiffs and Defendants and the amount in controversy exceeds $75,000.00. Subject-matter jurisdiction therefore exists under 28 U.S.C. § 1332.

11. Defendants have significant minimal contacts with this judicial district, having done substantial business in this district and purposefully availed themselves of the benefits and protections of the laws of this district. Defendants regularly transacted business in Georgia that includes marketing and selling these recalled products at the consumer level. They derive substantial revenue from their business transactions in Georgia and have purposely availed themselves of the privilege of doing business in Georgia. Defendants are therefore subject to specific personal jurisdiction in Georgia and this judicial district.

12. Plaintiffs have purchased and used recalled products in Cobb County, Georgia. Venue is proper under 28 U.S.C. § 1391(a) in that a substantial part of the events giving rise to the causes of action occurred in this judicial district.

III. Allegations

13. Concerns were raised about the safety and efficacy of aerosol sunscreens in 2019, when the FDA proposed a new rule to regulate nonprescription over-the-counter sunscreen drug products. The FDA asked manufacturers for safety data on chemical ingredients, including octocrylene (a harmful chemical that is not at issue here). See C.A. Downs, *Benzophenone Accumulates over Time from the Degradation of Octocrylene in Commercial Sunscreen Products*, 34 CHEM. RES. TOXICOL., 1046-1054 (2021). In the proposed rule, the FDA describes concerns about the safety of aerosol spray sunscreens. See Department of Health and Human Services, Food and Drug Administration, *Sunscreen Drug Products for Over-the-Counter Human Use*, 84 Fed. Reg. 6204, 6230 (Feb. 26, 2019). The FDA specifically raises concerns about inhalational toxicity: the potential that consumers might unknowingly inhale harmful chemicals present in the aerosol spray. *Id.* at 6231.

14. On July 14, 2021, Johnson & Johnson Consumer Inc., voluntarily recalled all lots of five NEUTROGENA® and AVEENO® aerosol sunscreen product lines to the consumer level. **Exhibit A.**

15. The aerosol sunscreen products subject to the recall are referred to as "recalled products."

16. J&J recalled the products in response to a citizen petition issued to the FDA on May 24, 2021, by Valisure LLC. **Exhibit B**. Valisure is an analytical pharmacy based in New Haven, Connecticut. Its mission is to help ensure the safety, quality, and consistency of medications and supplements in the market.

17. Valisure "tested and detected high levels of benzene, a known human carcinogen, in several brands and batches of sunscreen [made by Johnson & Johnson]." **Exhibit C.** Valisure then petitioned the FDA, asking for a recall of the sunscreen and requesting that the FDA "better define limits for benzene contamination in drug and cosmetic products." *Id.*

18. After the Valisure petition, Johnson & Johnson internally tested the aerosol and then through Johnson & Johnson Consumer Inc., issued a voluntary recall of specific NEUTROGENA® and AVEENO® aerosol sunscreen product lines. **Exhibit A.** In voluntarily recalling the products, Johnson & Johnson misrepresented the facts about the levels of benzene detected in NEUTROGENA® and AVEENO® aerosol sunscreen product lines. Specifically, Johnson & Johnson represented that the testing detected "low" levels of benzene in the recalled products. In reality, testing detected "high" levels of benzene, which was accurately described by Valisure when it petitioned the FDA to force a recall. Yet Johnson & Johnson chose

to misrepresent the level of benzene detected in the recalled products, downplaying the danger presented.

19. FDA research shows that the body absorbs enough of the chemical ingredients present in sunscreens for there to be significant concern about the safety of the ingredients present. See Murali K. Matta, *Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial*. 323 JAMA 256-257 (2020) (FDA-published study concluding that all six of the tested active ingredients administered in four different sunscreen formulations were systemically absorbed and had plasma concentrations that surpassed the FDA threshold for potentially waiving some of the additional safety studies for sunscreens).

20. Still, manufacturers like Johnson & Johnson have chosen not to address the issue as requested by the FDA. J&J, upon information and belief, has failed to provide the kind of safety data that the FDA requested in 2019.

21. Nonetheless, independent groups of scientists—like those at Valisure—have tested the products, detected the presence of carcinogens, and taken direct action to trigger safety recalls and corporate corrective action. Still, Johnson & Johnson characterizes the presence of benzene in the recalled aerosol sunscreens as *low* even though independent scientists characterize it as *high*.

22. Johnson & Johnson admits that through the testing performed, J&J detected the presence of benzene in the recalled products.

23. Johnson & Johnson issued an internal health hazard evaluation that grossly misrepresents the true dangers posed by the recalled, benzene-contaminated NEUTROGENA® sunscreen. Johnson & Johnson defends the recall by claiming that no acute or chronic adverse health consequences would be expected to result from using the recalled NEUTROGENA® spray sunscreen. Johnson & Johnson takes this defensive position even though extraordinary levels of benzene were detected in the recalled NEUTROGENA® sunscreen—both by Valisure and Johnson & Johnson—and it is incontrovertible that no safe level of benzene for human exposure exists.

24. J&J claims that benzene is not an intended ingredient in any of its sunscreen products.

25. There are a wide variety of aerosol spray products in the open market. J&J manufactures and sells many of these aerosol spray products. Some are unregulated and some are regulated. For those products that are regulated by the FDA, they generally fall into two categories: (i) drugs; or (ii) cosmetics. Sunscreen is regulated as a drug by the FDA.

26. J&J uses a propellant system for its NEUTROGENA® aerosol spray sunscreen wherein the substance (*i.e.*, sunscreen) is aerosolized and propelled out of an opening in the physical product to allow for consumer application.

27. There are several different kinds of aerosol propellants that can be used for aerosol spray products. Chlorofluorocarbons (CFCs) were once often used as propellants, but since the Montreal Protocol came into force in 1989, they have been replaced in nearly every country due to the negative effects CFCs have on Earth's ozone layer. The most common replacements of CFCs are mixtures of volatile hydrocarbons, typically propane, n-butane and isobutane. Dimethyl ether (DME) and methyl ethyl ether are also used. All these chemicals share the disadvantage of being flammable. Nitrous oxide and carbon dioxide are also used as propellants to deliver foodstuffs (for example, whipped cream and cooking spray). Medicinal aerosols such as asthma inhalers use hydrofluoroalkanes (HFA). More recently, liquid Hydrofluoroolefin (HFO) propellants have become more widely adopted in aerosol systems due to their relatively low vapor pressure, low global warming potential (GWP), and nonflammability. Manual pump sprays can be used as an alternative to a stored propellant.

28. J&J, for its NEUTROGENA® aerosol spray sunscreen, designed the propellant system to use a volatile hydrocarbon, isobutane. Isobutane is a colorless, odorless gas. Isobutane is commonly used in the petrochemical industry. Isobutane

is made through an isomerization[1] of butane. Butane is a liquefied petroleum gas that is found in crude petroleum.

29. J&J did not have appropriate systems in place to remove residual solvents from its finished aerosol spray drug products, including the recalled products. In fact, J&J did not have the ability to test for or remove impurities or residual solvents. Residual solvents are volatile organic chemicals, such as benzene, that are used or produced in the manufacture of its NEUTROGENA® aerosol spray sunscreen.

30. Because J&J did not have appropriate systems in place to remove impurities or residual solvents including benzene from its finished aerosol sunscreen products, the over-the-counter pharmaceuticals it manufactured, sold, and produced that are at issue in this case were contaminated with benzene, a known human carcinogen that is found in crude petroleum, which is one of the raw materials J&J uses in the manufacturing and supply chain process for the production of NEUTROGENA® aerosol spray sunscreen. Because crude petroleum is a raw material that J&J purposefully uses in the manufacturing and supply chain process to produce NEUTROGENA® aerosol spray sunscreen, J&J owed a duty of care to remove

[1] Isomerization refers to the process by which a molecule is transformed into an isomer with a different chemical structure.

impurities, residual solvents, and prevent harmful chemicals, including benzene, from being present in the finished product, a drug as regulated by the FDA.

31. Plaintiff Debra Cascio asserts claims for personal injuries relating to the dangers of the recalled NEUTROGENA® and AVEENO® products. Debra used multiple recalled products regularly over several years without having first been warned about the presence of high levels of benzene.

32. Debra began using NEUTROGENA® Beach Defense® as a daily skin protectant in or around 2016 when her home pool was finished being built. Debra routinely sprayed the recalled NEUTROGENA® Beach Defense® SPF 30, 50, 60, or 70 daily, among other recalled products, before walking her dogs. Debra's routine was to apply the sunscreen outside in a well-ventilated area. Debra routinely applied the recalled sunscreen to her neck, shoulders, arms, hands, legs, and feet. For facial sun protection, Debra's routine was to spray the recalled sunscreen on her hands and then apply it to her face. Debra would decrease her sunscreen usage on days when it was raining. Debra would likewise increase her sunscreen usage when she spent more time outdoors or exposed to the sun. For regular sun protection, Debra regularly applied the recalled product to her entire body 3-4 times daily.

33. Debra had many outdoor responsibilities and would regularly take care of outdoor chores. Skin care and skin cancer prevention have always been very important to Debra. Debra gardened daily. Debra was also responsible for pool

cleaning which required multiple days per week of maintenance. Debra purchased the recalled sunscreen at various retail stores, including Costco, Target, Walgreens, Publix, Kroger, and Walmart.

34. Debra stopped using the recalled product when she received an email from Costco on or about July 15, 2021, informing her about the recall. Upon information and belief, records of Debra's transaction purchasing recalled sunscreen still exist.

35. In or around July 2021, after a bone marrow biopsy, Debra was diagnosed with acute lymphoblastic leukemia ("ALL"). She experienced tremendous pain and suffering with a protracted hospital course. Debra underwent extensive treatment of her cancer at the Emory Winship Cancer Institute, including a stem cell transplant. Debra has continued to suffer complications of the ALL, treatment, and stem cell transplant. Debra is now in remission.

36. Debra's diagnosis is one that is rarely seen in adults without benzene exposure. It comes on the heels of persistent multi-year extensive usage of Defendant's recalled aerosol sunscreen products, which have been confirmed to contain benzene with high levels that are likely to cause acute and chronic adverse health consequences. It is well settled that the kind of leukemia that Debra has suffered is known to be caused by exposure to benzene. The kind of leukemia that Debra has suffered is likely to result from multi-year usage of benzene contaminated

Neutrogena sunscreen. Even exposure to benzene at levels under 1 part per million may cause the kind of leukemia that Debra has suffered.

37. Debra's habit was to purchase the NEUTROGENA® Beach Defense® aerosol spray sunscreen in SPF levels 30, 50, 60, or 70. She did not have a practice of purchasing other brands besides NEUTROGENA®. There is no meaningful dispute that this sunscreen was recalled because it was grossly contaminated with dangerous levels of benzene, a known human carcinogen in which no safe level of exposure exists. The levels detected in the recalled NEUTROGENA® sunscreen range from about 11 to 26 parts per million. These levels are extraordinarily high and would be expected to cause acute or chronic adverse health consequences to the unaware consumer.

38. From 2016 to 2021, Debra used recalled NEUTROGENA® aerosol spray sunscreen regularly. All the NEUTROGENA® aerosol spray sunscreen that she used was contaminated with benzene because all the products used isobutane as its propellant system. The sunscreen was ultimately contaminated with benzene because residual solvents that J&J uses in the manufacturing and supply chain process were not removed from the finished product. Moreover, because one of the raw materials used in the manufacturing and supply chain process is crude petroleum, J&J knew or should have known that contamination with residual solvents or volatile hydrocarbons including benzene would be highly probable and

expected to occur. Nonetheless, J&J chose not to implement appropriate systems or controls to remove residual solvents, including harmful carcinogens like benzene, from their OTC aerosol spray sunscreen drugs.

39. Benzene, a human carcinogen, is known to cause acute leukemia, which Debra has suffered. Because the presence of benzene in NEUTROGENA® aerosol sunscreen was not disclosed to her, Debra was unable to prevent her exposure to this dangerous chemical.

40. The dangers disclosed by Johnson & Johnson in the recall were not known, available, or knowable to Debra before that time. This lawsuit is therefore timely and brought within the prescribed limitations period based upon the legal principles of accrual, discovery, and tolling.

41. Defendants owed a duty not to cause Plaintiff an unreasonable risk of injury due to a defect or lack of safety or efficacy with the recalled aerosol sunscreen products. This includes a duty to conduct adequate and well controlled testing before marketing and during postmarketing surveillance.

42. But Defendants provided consumers with false and misleading information about product safety and efficacy even though they knew or should have known about the dangers disclosed in the recall before July 14, 2021.

43. Defendants also chose to market and sell the defective products in a way to maximize the sales but minimize health and safety, failing to conduct

adequate testing or failing to appropriately inform consumers about the presence of benzene before the Valisure testing.

44. Defendants wrongfully withheld from the information sphere the true risk and benefits of their aerosol sunscreen products, encouraging use to protect against melanoma while failing to warn about the presence of benzene. Because of this negative propaganda campaign, Defendants helped convince consumers to use the recalled products to protect against skin cancer, but these consumers were oblivious to the fact that the products contained high levels of benzene, which causes cancer.

45. Because Defendants wrongfully withheld the true information about these dangers, there has been pervasive use of defective products when other safer alternatives are available.

46. Indeed, safer alternatives to hydrocarbon-based aerosol propellants exist, including but not limited to dimethyl ether (DME) and methyl ethyl ether (MEE). Such safer alternatives do not carry the same risk of contamination with residual solvents, including benzene. J&J, however, chose not to use any safer alternative and instead used a hydrocarbon-based aerosol propellant, which resulted in contamination with benzene.

47. Defendants negligently, willfully, wantonly, and/or recklessly failed to warn about the true risks, dangers, defects, and disadvantages of the recalled

products. Defendants instead suppressed the true risks and benefits, including the presence of harmful chemicals in the product.

48. Defendants knew or should have known that the recalled products are not safe for the intended and ordinary purpose for which they are sold. These recalled products are likely to cause and do cause serious injury and death.

49. Plaintiff makes no claim here for fraud on the FDA. Rather, Plaintiff's claims center on the Defendants' failure to warn about the dangers they knew or should have known. These defendants knew or should have known about these dangers through appropriate review, testing, and postmarketing surveillance. There is a presumption against federal preemption of state laws that operate in traditional state domains. It is black-letter law that manufacturers must warn of dangers that they know or should know exist with ordinary use of their products, and this duty continues after sale. State law claims may therefore parallel federal-law duties existing under the FDA regulations. See, e.g., *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769-70 (5th Cir. 2011).

50. Defendants have underreported and misreported adverse-event information about the propensity of the recalled products to cause serious injury, complications, and death. They have misrepresented the efficacy and safety of recalled products generally, downplaying the risks and overstating the benefits through various means and media, actively and intentionally misleading the FDA

and the public at large.

51. At all times relevant hereto, Plaintiff was exposed to and regularly used the recalled products in an intended or reasonably foreseeable manner. Plaintiff used the recalled products without knowing about the unreasonably dangerous characteristics. Had the unreasonably dangerous features of the product been made known, Plaintiff would never have used the products. She would instead have used other safer alternatives in existence and available on the market.

52. The harm caused by the recalled products far outweigh the benefits, rendering the product unreasonably dangerous to an extent beyond that which an ordinary consumer would consent.

53. Withholding knowledge about the true dangers while persisting with the defective marketing message is a manufacturing of consent. Plaintiff never would have consented to using the recalled defective products had the true dangers, risks, and benefits first been made known.

54. The recalled products are more dangerous than available alternative products. Defendants could have designed and tested the recalled products to make them less dangerous—without benzene. A less risky design or formulation was attainable at the time of manufacture and sale.

55. At the time the recalled products, including the subject products, left

Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended utility.

56. Defendants' defective design was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the recalled products.

57. Because of the unreasonably dangerous condition of their recalled products, Defendants are liable for negligence, breach of warranty, and for product liability.

IV. Counts

Count One – Product Liability – Design Defect

58. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

59. The recalled products are defectively designed in that they are unreasonably dangerous and do not meet the reasonable expectations of the ordinary consumer or user as to safety. The warnings, moreover, do not adequately cover the defects made known by the voluntary recall (July 14, 2021), including:

i. The recalled products are defective in design and formulation;

ii. The dangers are beyond that which an ordinary consumer would contemplate;

iii. The recalled products are unreasonably dangerous given the

presence of benzene, a volatile organic compound (VOC) that causes cancer and other serious illnesses;

iv. The recalled products are unreasonably dangerous because they are consumer drugs that are manufactured with a hydrocarbon-based aerosol propellant system that predictably results in contamination with benzene, a known human carcinogen for which no safe level of human exposure exists;

v. The products are unreasonably dangerous when used in a reasonably anticipated manner;

vi. Defendants did not timely disclose the results of earlier tests or studies of the recalled products showing the presence of benzene or VOCs.

vii. Using the recalled products presents a risk of serious injury that outweighs any potential utility of the products;

viii. Defendants knew or should have known at the time of marketing and continued marketing and selling the recalled products, including the subject products, that ordinary use could result in cancer and other severe illnesses and injuries;

ix. Instead of timely disclosing the dangers—the risks of cancer—Defendants continued to market, sell, and promote the recalled products until Valisure petitioned the FDA;

x. The lack of adequate postmarketing surveillance; and

xi. The existence of safer alternative designs and formulations making them less prone to causing cancer and other adverse health conditions, including but not limited to aerosol propellant systems based on DME or MEE instead of hydrocarbons.

60. The recalled products were defective in design when they left the possession of Defendants' control. There was no substantial change from the time they left the possession of Defendants until they reached Plaintiff.

61. There was a safer and more practical alternative design that Defendants could have used at the time that they made and sold the recalled products; to wit, a DME or MEE aerosol propellant system as opposed to hydrocarbon.

62. Plaintiff was caused substantial harm and suffered both economic and noneconomic damages by the design defects in the recalled products, including loss of enjoyment of life.

63. The recalled products are unreasonably dangerous and defective, unfit, and unsafe for intended use and reasonably foreseeable uses and do not meet or perform to the expectations of the ordinary consumer.

64. The recalled products are defective in design because they fail to perform as safely as persons who ordinarily use the products would expect at time of use.

65. Plaintiff used the recalled products in a manner that was reasonably foreseeable to the Defendants.

66. Plaintiff could not have by the exercise of reasonable care discovered the defective conditions or perceived the unreasonable dangers and unreasonably dangerous propensities before July 14, 2021.

67. As a result of the foregoing design defects, the recalled products create risks to the health and safety of its users that are far more significant and devastating than the risks posed by other products available, and which far

outweigh the utility of the recalled products.

68. Defendants have intentionally and recklessly designed the recalled products with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their economic interests above the health and safety of the Plaintiff.

69. As a proximate result of the Defendants' design, Plaintiff has been injured seriously and has sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

Count Two – Product Liability – Failure to Warn

70. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

71. The recalled products are dangerous when used as intended. Defendant failed to give adequate warnings about the dangers and propensities of the products to cause unreasonable harm when used as intended.

72. The products were used as intended. Defendants either knew or should have known, through postmarketing surveillance and otherwise, that the product could create the kinds of dangers complained about when used as intended and in its ordinary and customary manner.

73. No timely adequate warning was made about the kinds of dangers described here.

74. Plaintiff was caused substantial harm and suffered both economic and noneconomic damages because of the failure to warn about the danger.

75. At the time the Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the recalled products, they knew or should have known that the products present an unreasonable danger when put to intended and/or reasonably anticipated use.

76. Defendants knew or should have known, and therefore should have warned about the following dangers:

i. The recalled products are defective in design and formulation;

ii. The dangers are beyond that which an ordinary consumer would contemplate;

iii. The recalled products are unreasonably dangerous given the presence of benzene, a volatile organic compound (VOC) that causes cancer and other serious illnesses;

iv. The recalled products are unreasonably dangerous because they are consumer drugs that are manufactured with a hydrocarbon-based aerosol propellant system that predictably results in contamination with benzene, a known human carcinogen for which no safe level of human exposure exists;

v. The products are unreasonably dangerous when used in a reasonably anticipated manner;

vi. Defendants did not timely disclose the results of earlier tests or

studies of the recalled products showing the presence of benzene or VOCs.

vii. Using the recalled products presents a risk of serious injury that outweighs any potential utility of the products;

viii. Defendants knew or should have known at the time of marketing and continued marketing and selling the recalled products, including the subject products, that ordinary use could result in cancer and other severe illnesses and injuries;

ix. Instead of timely disclosing the dangers—the risks of cancer—Defendants continued to market, sell, and promote the recalled products until Valisure petitioned the FDA;

x. The lack of adequate postmarketing surveillance; and

xi. The existence of safer alternative designs and formulations making them less prone to causing cancer and other adverse health conditions.

77. Defendants failed to warn about the level of research and testing of the recalled products, including the true results of the available testing, and known information from complaints and adverse events.

78. The risks associated with the recalled products are of such a nature that consumers could not have recognized the potential harm without the information disclosed via the recall.

79. The recalled products were defective and unreasonably dangerous at the time of release into the stream of commerce due to the inadequate warnings, labeling and/or instructions accompanying the product.

80. When used by Plaintiff, the recalled products were in the same

condition as at the time of manufacture, inspection, marketing, labeling, promoting, distributing and sale.

81. Defendants willfully, intentionally, recklessly, deliberately, negligently, and/or and maliciously misrepresented the safety, risks, and benefits to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

82. As a proximate result of the Defendants' failure to warn, Plaintiff has been injured seriously and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of health, comfort, and economic damages.

Count Three – Negligence/Negligent Design, Manufacture & Sale

83. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

84. Defendants negligently designed, manufactured, supplied, distributed, and sold the recalled products.

85. Plaintiff was caused substantial harm and suffered both economic and noneconomic damages because of the negligent, design, manufacture, and sale.

86. The negligence was a proximate cause of Plaintiff's harm and damages.

87. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instruction, warning, sale, marketing, safety

surveillance and distribution of the recalled products to avoid exposing Plaintiff to foreseeable and unreasonable risks of harm.

88. Defendants breached their duty of care to Plaintiff, in the manufacture, design, labeling, warning, instructions, sale, marketing, safety surveillance, and distribution of the recalled products.

89. Defendants knew or should have known that the recalled products were unreasonably dangerous when used ordinarily and as intended.

90. Defendants knew or should have known that the recalled products when used as they marketed and sold are unreasonably dangerous and have the defects described herein.

91. Defendants knew or reasonably should have known that the recalled products are more dangerous or likely to be dangerous when as intended or in a reasonably foreseeable manner. Defendants had a duty to avoid causing an unreasonable risk of harm to Plaintiff.

92. At the time of manufacture and sale, Defendants knew or should have known that using the recalled products for intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering and severe injuries, including cancer, autoimmune disorders, and cardiac injury.

93. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the recalled products.

94. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would not have engaged in the acts and omissions complained about herein.

95. As a proximate result of the Defendants' design, manufacture, marketing, sale, and/or distribution of the recalled products, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of health, comfort, and economic damages.

Count Four – Negligent Failure to Warn

96. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

97. The recalled products are dangerous when used as intended. Defendants failed to give adequate warnings about the dangers and propensities of the product to cause unreasonable harm when used as intended.

98. The products were used as intended. Defendants either knew or should have known, through postmarketing surveillance and otherwise, that the recalled

products could create the kind of dangers described here when used as intended and in its ordinary and customary manner.

99. No timely adequate warning was made about the kind of danger described here.

100. Plaintiff was caused substantial harm and suffered both economic and noneconomic damages because of the failure to warn about these dangers.

101. At the time the Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the recalled products, they knew or should have known that the products present an unreasonable danger to patients when put to intended or reasonably anticipated use.

102. Defendants owed a duty to avoid causing Plaintiff an unreasonable risk of injury by providing adequate warnings.

103. Defendants failed to warn about the level of research and testing of the recalled products properly and adequately, and failed to so warn about the propensities of the product to cause cancer and other serious injuries and health problems.

104. As a proximate result of the Defendants' negligent failure to warn, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of health, comfort, and economic damages.

Count Five – Misrepresentation

105. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

106. Defendants falsely and fraudulently represented to the public that the recalled products had been tested and were safe and effective.

107. The representations made by Defendants were, in fact, false. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were indeed false. Yet Defendants negligently, willfully, wantonly, and recklessly disregarded the inaccuracies in their representations about the dangers of the recalled products.

108. These representations were made by Defendants with the intent of defrauding and deceiving the public, and also inducing consumers at large to purchase the recalled products for use, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers including Plaintiff.

109. In representations to Plaintiff and the public, Defendants fraudulently concealed and intentionally or recklessly omitted the following material information:

i. That the recalled products are not as safe as other similar products available;

ii. That the recalled products are not more effective than other similar products available;

iii. That the recalled products are unreasonably dangerous because they are consumer drugs that are manufactured with a hydrocarbon-based aerosol propellant system that predictably results in contamination with benzene, a known human carcinogen for which no safe level of human exposure exists;

iv. That the recalled products contain harmful chemicals due to the presence of residual solvents that are not removed from the finished product;

v. That the recalled products are not appropriately tested for safety and efficacy, including the failure to study the products as obligated under FDA rules and regulations;

vi. That the likelihood of an adverse event requiring serious medical attention with the recalled products is much higher than with other similar products available;

vii. That the testing and surveillance shows the recalled products have a higher risk of adverse effects beyond those associated with other similar products available;

viii. That Defendants deliberately failed to follow up on the adverse results from studies and formal and informal reports and buried and/or misrepresented those findings;

ix. That Defendants deliberately chose to forego studies that might reveal the true levels of benzene present and rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to the Plaintiff or the regulatory authorities;

x. That Defendants were aware of dangers beyond those associated with other similar products available;

xi. That the recalled products are defective, and that they cause dangerous and adverse health consequences, including cancer;

xii. That users of the recalled products need to be medically monitored; and

xiii. That the recalled products contain benzene, which is harmful to humans, and causes cancer, serious injury, and death;

110. Defendants were under a duty to disclose the defective nature of the recalled products, including but not limited to the heightened risks of cancer, injury, and death.

111. Defendants had access to the full material facts concerning the defective nature of the recalled products and the propensity to cause serious injury and death.

112. Defendants' concealment and omissions of material fact were done negligently, purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiff and consumers to purchase the recalled products; and/or to mislead Plaintiff and consumers into reliance and cause Plaintiff to use the recalled products.

113. At the time these representations were made, and at the time Plaintiff used the recalled products, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

114. Defendants knew and had reason to know that the recalled products could and would cause serious injury, and that the products are inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise

downplayed warnings.

115. In reliance upon these false representations, Plaintiff was induced to and did use the recalled products in a pervasive manner. Plaintiff thereby sustained severe and permanent personal injuries and damages.

116. Defendants knew or had reason to know that Plaintiff and consumers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the recalled products, as described in detail herein.

117. Plaintiff reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the recalled products.

118. Having knowledge based upon Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring Plaintiff, the public, and consumers at large, that the recalled products are safe for use and as safe or safer than other products available on the market.

119. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed, and suppressed certain results of testing and research to Plaintiff and the public at large.

120. Defendants had a duty when disseminating information to the public

to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and the United States Food and Drug Administration.

121. The information distributed to the public, the FDA, and Plaintiff by Defendants included, but was not limited to websites, information presented at point of sale and in marketing, information disseminated by company representatives, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the recalled products.

122. Defendants intentionally made material misrepresentations to the public, including Plaintiff, regarding the safety of the recalled products specifically that they did not have dangerous and/or serious adverse health safety concerns, and that the recalled products were safe or safer than other similar products available.

123. Defendants intentionally failed to purchasers and the public, including Plaintiff, of the dangers and risk of injury.

124. Defendants chose to falsely market the purported safety, efficacy, and benefits of the recalled products instead.

125. Defendants' intent and purpose in making these misrepresentations

was to deceive and defraud the public and Plaintiff; to gain the confidence of the public and Plaintiff; to falsely assure them of the quality and fitness for use of the recalled products; and induce Plaintiff and the public to purchase and continue to use the recalled products.

126. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and in advertisements that the recalled products have beneficial properties and do not present serious health risks.

127. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

128. These representations, and others made by Defendants, were made with the intention of deceiving and defrauding Plaintiff and the public, and were made in order to induce Plaintiff to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the recalled products.

129. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the recalled products to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other

alternatives.

130. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiff and consumers into a false sense of security, so that Plaintiff and consumers would rely on Defendants' representations, and Plaintiff and others would request and purchase the recalled products.

131. At the time the representations were made, Plaintiff did not know the truth about the dangers and serious health and safety risks inherent in the use of the recalled products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

132. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the recalled products, Plaintiff would not have purchased or used, or relied on the recalled products.

133. Defendants' wrongful conduct constitutes fraud, suppression, concealment, and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

134. As a direct and proximate result of Defendants' conduct, Plaintiff experienced significant mental and physical pain and suffering, have sustained

permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, other damages, including loss of enjoyment of life.

135. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, punitive damages, together with interest, costs of suit, and such further relief as the Court deems equitable and just.

Count Six – Breach of Implied Warranty of Merchantability

136. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

137. Defendants were regularly in the business of selling the recalled products at all times relevant.

138. The recalled products are not suitable or fit for the ordinary purpose for which they are used.

139. Plaintiff was caused substantial harm and suffered both economic and noneconomic damages as a result of this breach of warranty.

140. At relevant times, the Defendants intended that the recalled products be used for the purposes and in the manner Plaintiff used it and the Defendants impliedly warranted that the recalled products are of merchantable quality, safe and fit for such use, and are adequately tested.

141. Defendants were aware that consumers, including Plaintiff would use the recalled products in the manner that was foreseeable.

142. Plaintiff was at all relevant times in privity with the Defendants.

143. The recalled products were expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which they manufactured and sold.

144. The Defendants breached various implied warranties with respect to the recalled products, including the following particulars:

i. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the recalled products are safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with use.

ii. Defendants represented that the products are safe or safer than other alternative products and fraudulently concealed information, which demonstrated it was not as safe or safer than alternatives available on the market;

iii. The Defendants represented that the recalled products were as efficacious than other alternative treatments and fraudulently concealed information about the true efficacy; and

iv. In reliance upon the implied warranties, Plaintiff used the recalled products as prescribed in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

145. Defendants breached their implied warranties to Plaintiff in that the recalled products are not of merchantable quality, safe and/or fit for intended use, or adequately tested, in violation of common law principles.

146. As a proximate result of the breaches of warranty, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, comfort, and economic damages.

Count Seven – Breach of Implied Warranty of Fitness

147. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

148. Defendants were regularly in the business of selling the recalled products at all times relevant.

149. Defendants knew that the purchasers, consumers, and Plaintiff were relying on their skill or judgment to provide a suitable product.

150. The recalled products are not suitable or fit for the particular purpose for which they are used.

151. Plaintiff was caused substantial harm and suffered both economic and noneconomic damages because of this breach of warranty.

Count Eight – Loss of Consortium

152. Plaintiffs re-allege all the preceding allegations as though fully set forth here.

153. Before the diagnosis of leukemia made the basis of this suit, Plaintiffs Dan and Debra Cascio were legally married, as husband and wife. Each became entitled to the companionship, fellowship, cooperation, assistance, affection, services, comfort, support, society, guidance, material services, and consortium of their respective spouses during the period of coverture. Each spouse had a right to the continuation of the normal marital relationship.

154. Because of the rare leukemia diagnosis suffered by Debra, which was caused by her unknowing exposure to benzene, a dangerous carcinogen, Plaintiff Dan Cascio was deprived, has been deprived, and will in the future be deprived of the companionship, fellowship, cooperation, assistance, affection, services, comfort, support, society, guidance, material services, and consortium of his spouse, Debra.

155. As a direct and proximate result of the physical, mental, and emotional pain and suffering of Debra caused by the wrongdoing of Defendants, Plaintiff Dan Cascio has suffered disruption of the normal marital relationship to which he became entitled. Because of Defendants' wrongdoing, Dan Cascio will continue to suffer serious noneconomic damages in the form of loss of consortium, as described herein.

V. Prayer for Relief

WHEREFORE, Plaintiff requests the following relief:

i. That process issue and the Defendants be served in accordance with the Federal Rules of Civil Procedure;

ii. That Plaintiffs be awarded compensatory damages, including medical expenses, subrogation expenses, lost wages, loss of earning capacity, loss of enjoyment of life, future economic damages, general noneconomic damages, pain and suffering, and for personal injury in an amount to be determined by the enlightened conscience of a jury;

iii. That Plaintiffs be allowed to amend this Complaint in accordance with the Federal Rules of Civil Procedure;

iv. That the Plaintiffs be awarded punitive damages;

v. That Plaintiffs have a trial by jury as to all issues; and

vi. That Plaintiffs be awarded such other relief as this Court may deem just and proper.

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Submitted: July 14, 2023

/s/ W. Lewis Garrison, Jr.
GA Bar # 286815
William L. Bross
ASB-9703-O71W
Application for Pro Hac Vice
To Be Filed
HENINGER GARRISON DAVIS
2224 1st Avenue North
Birmingham, AL 35203
Tel: 205-326-3336
Fax: 205-326-3332
lewis@hgdlawfirm.com
william@hgdlawfirm.com

Francois M. Blaudeau
ASB-7722-D32F
Application for Pro Hac Vice
To Be Filed
Evan T. Rosemore
ASB-3760-N10B
Application for Pro Hac Vice
To Be Filed
SOUTHERN MED LAW
2762 BM Montgomery St., Ste. 101
Homewood, AL 35209
Tel: 205-564-2741
francois@southernmedlaw.com
evan@southernmedlaw.com